Summary of
Revised DRAFT Medical Cannabis Regulations

A new draft of proposed medical Cannabis regulations has been developed by the Executive Committee of the Medical Marijuana Commission, with review and input from the Policy Committee, the Assistant Attorney General, and the policy staff of the Secretary of Health and Mental Hygiene. It takes into account the numerous suggestions contained in the 57 submissions of public comment pursuant to publication on January 23, and the **amendments made by H.B. 490 to the medical Cannabis law** now pending in the General Assembly, which passed the House of Delegates on March 19, 2015. This summary briefly outlines the highlights of changes in this draft proposal, dated March 20, from the January 23 proposal.

One prominent new feature is that, assuming passage of the new legislation, medical marijuana will henceforth be referred to as medical Cannabis, to help distinguish it from illegal "marijuana," and to recognize the proper scientific nomenclature for the medicine. The Commission will be renamed as well.

It must be stressed that this March draft, like our previous drafts, has been reviewed under a compressed timeline as the medical marijuana/Cannabis law is being simultaneously considered in the General Assembly. We are working expeditiously to establish a medical Cannabis program to meet the urgent need of thousands of Marylanders for safe and affordable medical Cannabis.

Definitions

Key definitions that are revised or added since the January 23 publication include: caregiver, licensed dispensary, licensed grower, licensed processor, medical Cannabis, medical Cannabis concentrate, medical Cannabis-infused product, medical Cannabis finished product, usable Cannabis, and 30-day supply.

Because medical Cannabis products may contain THC, we have amended the term "30-day supply" to include 36 grams of THC in addition to 120 grams of dried leaves and flowers of Cannabis plant.

Patients

In order to establish patient identity, a patient will register on-line with the Commission before they see a physician. Patients need not be Maryland residents. Patients will get a unique identification number that they will use with their physicians and with their dispensaries.

Patients may obtain an identification card from the Commission for a fee of $50. This is comparable to the fee for a Driver's License. The card will expire after two years.

Physicians

Physicians will not have to pay any fee, nor will they have to be "approved" by the Commission. They will register with the Commission regarding the conditions that they propose to treat including severe conditions for which other medical treatments have been ineffective and if the symptoms reasonably can be expected to be relieved by medical use of Cannabis. They will not have to fulfill any educational requirement to register or renew their registration. A physician will have to attest that a standard patient evaluation will be completed, including a history, a physical examination, a review of symptoms, and other pertinent medical information. Their registration is valid for 2 years. H.B. 490 would also bar the Commission from limiting treatment of certain conditions or diseases to particular medical specialties. H.B. 490 was amended to eliminate the physicians' annual reporting requirement.

Written Certifications

A patient must obtain a written certification from a registered physician. Physicians will determine if a patient qualifies for a written certification after a standard assessment. Special screenings will not be required. The physician and patient must have a bona-fide physician-patient relationship. We contemplate that the written certification will be electronically transmitted to the Commission. A physician may include a written statement certifying that, in the physician's professional opinion, a 30–day supply of medical cannabis would be inadequate to meet the medical needs of the qualifying patient.

Caregivers

Patients may designate caregivers and notify the Commission of the designation by using the Commission's website. The caregivers will then need to register with the Commission and obtain identification cards. Caregivers must be 21-years old.

Processing Concentrates and Medical Cannabis-Infused Products

H.B. 490 would create a third class of licensee of those who would process Cannabis into concentrates and medical Cannabis-infused products. The annual fee for a processor would be $40,000.

Licensing

The period for initial licenses would be 4 years, with renewals then required every two years. The proposed regulations would simplify the application process to delete the submission of a "footnoted financial statement" but will require an audited financial statement. Applicants would have to demonstrate adequate capitalization for the particular business plan that they propose. Change of ownership can go forward unless the Commission objects within 45 days.

Licensee Premises

The proposed draft regulations streamline many of the specific details set forth in the previous proposal. The Commission will review the specifications of the applications to assure that security concerns are satisfied. Details regarding surveillance and alarm systems were revised to consider cost and practicality. Many requirements were revised to rely upon the licensee's standard operating procedures.

Growers

The requirements of growing controls were revised to rely upon the licensee's standard operating procedures.

The confusing concept of "satellite" facility is being eliminated by H.B. 490. Growers may apply to operate a dispensary near the grow facility and to operate a dispensary that is not close to the grow facility.

The 2016 date that limits the number of growers to 15 is being extended to 2018 by H.B. 490. The annual fee for a grower would be $125,000 per year.

Quality Control

The draft proposal continues to put a very high priority on maintaining the purity of the medicine by requiring testing by accredited independent testing laboratories. H.B. 490 authorizes the Commission to register and inspect independent testing laboratories.

Processor Operations

The proposed regulations do not detail the solvents or methods of preparation of concentrates, but rely upon the establishment of standard operating procedures that will be enforced.

Dispensaries

The draft proposal provides that a secure "room" is adequate for storing inventory rather than a "vault."

The draft proposal clarifies that the location of a dispensary operated by a licensed grower does not count toward the two dispensary licenses the Commission may award in each Senatorial district. The annual fee for dispensaries would be $40,000.

Dispensaries will not be required to have a licensed clinical director, but application review will include plans to counsel patients and caregivers in the use of medical Cannabis and to train dispensary agents.

The draft proposal would permit dispensaries to directly deliver medical Cannabis to patients in their homes.

H.B. 490 was amended to require that dispensaries gather and report data to the Commission on patients (omitting any personal information that identifies a patient) regarding numbers, county of residence, numbers of various medical conditions, the amount and types of medical Cannabis dispensed, and if available, a summary of clinical outcomes including adverse events and cases of suspected diversion.

Academic Medical Centers

H.B. 490 has been amended to eliminate academic medical centers from the medical Cannabis program.

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